K083469 1/1

510(k) Summary

Date Prepared:	November 21, 2008 FEB 13 2009
Sponsor:	MetaSurg 16350 Park Ten Place, Suite 101 Houston, TX 77084
Company Contact:	Mark Myers Phone: (281) 398-5656 Fax: (281) 398-5660
Device Trade Name:	MetaSurg Cannulated Titanium Hemi Implant
Classification Name:	Toe joint phalangeal (hemi-toe) polymer prosthesis (21 CFR 888.3730, Product Code KWD, Class II)
Common Name:	Hemi Toe Implant
Substantial Equivalence:	Documentation is provided to demonstrate the MetaSurg hemi implant to be substantially equivalent to the Vilex hemi implant (K023684) and the BioPro hemi implant (K041595). The methods used to establish equivalence are indications for use, material of construction, sizes, shape and implant type.
Device Description:	The MetaSurg cannulated titanium hemi implant is designed to be an anatomical replacement for the base of the phalanax. The implant is offered in 5 sizes ranging from 15 – 23mm in diameter.
Intended Usage:	The MetaSurg cannulated titanium hemi implant is indicated for use in the treatment of degenerative arthritis in the 1st metatarsal joint along with the following clinical conditions: Hallux Limitus or Hallux Rigidus, Hallux Valgus and pain or instability in the metatarsophalangeal joint. The MetaSurg cannulated titanium implant is intended for press fit, uncemented use. The MetaSurg cannulated titanium hemi implant is intended for single use only.
Material:	Titanium Alloy (Ti-6AL-4V ELI)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MetaSurg
% Mr. Mark Myers
16350 Park Ten Place, Suite 101
Houston, TX 77084

FEB 13 2009

Re: K083469
Trade/Device Name: MetaSurg Cannulated Titanium Hemi Implant
Regulation Number: 21 CFR 888.3730
Regulation Name: Toe joint phalangeal (hemi-toe) polymer prosthesis
Regulatory Class: II
Product Code: KWD
Dated: February 2, 2009
Received: February 3, 2009

Dear Mr. Myers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K083469

Device Name: *MetaSurg Cannulated Titanium Hemi Implant*

Indications for Use:

The MetaSurg cannulated titanium hemi implant is indicated for use in the treatment of degenerative arthritis in the 1st metatarsal joint along with the following clinical conditions: Hallux Limitus or Hallux Rigidus, Hallux Valgus and pain or instability in the metatarsophalangeal joint.
The MetaSurg cannulated titanium hemi implant is intended for press fit, uncemented use.

The MetaSurg cannulated titanium hemi implant is intended for single use only.

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K083469